Health Research Authority

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19 December 2019

Professor Joan K Morris
Population Health Research Institute
St George's University of London
Cranmer Terrace
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Dear Professor Morris

Application title:	**Linked de-identified research database for congenital anomaly outcomes**
CAG reference:	**19/CAG/0220 (to replace PIAG 2-08(e)/2002)**
IRAS project ID:	**188069**
REC reference:	**16/EM/0440**

Thank you for submitting a **research** application under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') to process confidential patient information without consent.

Supported applications allow the controller(s) of the relevant data sources, if they wish, to provide specified information to the applicant for the purposes of the relevant activity without being in breach of the common law duty of confidence. Support provides a lawful basis to allow the information to be processed by the relevant parties for the specified purposes without incurring a breach of the common law duty of confidence only. Applicants must ensure the activity remains fully compliant with all other relevant legislation.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Health Research Authority on whether application activity should be supported, and if so, any relevant conditions. This application was considered at the CAG meeting held on 05 December 2019.

This outcome should be read in conjunction with the provisional outcome letter dated 12 December 2019.

Health Research Authority decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The application to allow the disclosure of confidential patient information from localised regional registers and Public Health England to St George's University of London and subsequent disclosures to NHS Digital, NHS Wales Informatics Service is fully supported, subject to compliance with the standard conditions of support.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

Context

Purpose of application

This application from St George's University of London set out the purpose of medical research through the creation of a research database into the outcome of children affected by congenital abnormalities registered in the UK prior to 01 April 2015. The application has existing support under application reference PIAG 2-08(e)/2002; however, a refreshed application became necessary due to a change in controller for the proposal.

The application support to enable the BINOCAR regional registers to transfer specified legacy data to St George's University of London to enable linkage with health, mortality and educational data with a view to creating a congenital anomaly outcomes research database to facilitate research into the outcomes of children affected by congenital anomalies. Support is also requested to enable the disclosure of complete BINOCAR legacy datasets relating to the Northern Congenital Abnormality Survey (NoCAS) and the South West Congenital Anomaly Register (SwCAR) from Public Health England. Ongoing linkages are proposed with administrative health datasets, mortality data and educational outcomes. The applicant is seeking support for the ongoing processing and retention of confidential patient information for the complete BINOCAR legacy dataset until June 2021. The database will only contain legacy information registered prior to 01 April 2015; no newly registered congenital anomalies will be included.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients registered in the following regional congenital anomaly registers will be transferred into the database: 1. Congenital Anomaly Register for Oxfordshire, Berkshire and Buckinghamshire (CAROBB) - births from 1991 to 31 March 2015; 2. East Midlands and South Yorkshire Congenital Anomaly Register (EMSYCAR) - births from 1997 to 31 March 2015;

	3. South West Congenital Anomaly Register (SWCAR) – births from 2002 to 31 March 2015; 4. Northern Congenital Abnormality Survey (NorCAS) – births from 1985 to 31 March 2015; 5. Wessex Antenatally Detected Anomalies Register (WANDA) – births from 1994 to 31 March 2015.
Data sources	1. Hospital Episodes Statistics (HES), NHS Digital 2. ONS mortality data, NHS Digital 3. National Pupil Database, Department for Education
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID 4. Date of birth 5. Date of death 6. Postcode (Unit level) 7. Ethnicity
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode (Unit level) 4. Sex 5. Ethnicity

Confidentiality Advisory Group advice

The applicant's response to the provisionally supported outcome was considered by a sub-committee of the CAG.

Confirm whether there is any intention to link with the CPRD dataset in the future.

The applicant confirmed that they did not intend to link the BINOCAR data with the CPRD dataset in the future. The Sub-Committee was satisfied by this assurance.

Confirm whether Public Health England would be retaining a linkage file when the study dataset has been anonymised. If so, please clarify under what legal basis this would be retained.

The applicant advised that Public Health England would not retain a linkage file when the study dataset has been anonymised. Only the linkage organisations (NHS Digital and Department for Education) will have access to linkage files and these will be deleted upon completion of linkages. The Sub-Committee was satisfied by the clarification provided.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the standard conditions of support as set out below.

Specific conditions of support

1. Provide an updated copy of the website text for review within three months of the date of the final outcome letter.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 04 February 2019**

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed: NHS Digital and St George's Medical School have confirmed 'Standards Met' grades on DSPT 2018/19 (NHS Digital email 11 September 2019). Department for Education has confirmed assurance (NHS Digital email 11 September 2019).**

As the above conditions have been accepted and met, this letter provides confirmation of final support. I will arrange for the register of approved applications on the HRA website to be updated with this information.

Application maintenance

Annual review

Please note that this support is subject to submission of an annual review report to show how you have met the conditions or report plans, any public benefits that have arisen and action towards meeting them. It is also your responsibility to submit this report every 12 months for the entire duration that confidential patient information is being processed without consent.

Reminders are not issued so please ensure this is provided annually to avoid jeopardising the status of the support.

The annual review should be provided no later than **19 December 2020** and preferably 4 weeks before this date.

Submission of an annual review in line with this schedule remains necessary even where there has been a delay to the commencement of the supported activity, or a halt in data processing.

For an annual review to be valid, there must be evidence that the relevant DSPT submission(s) are in place and have been reviewed by NHS Digital. Please plan to contact NHS Digital in advance of the annual review submission, and submit evidence in the form of direct email from NHS Digital to evidence that 'standards met' grade are in place for all relevant DSPT submissions detailed in the conditions of support above.

Register of Approved Applications

All supported applications are listed in the published Register of Approved Applications. It is a statutory requirement for the Register to be published and it is available on the CAG section of the Health Research Authority website.

Changes to the application

The application and relevant documents set out the scope of the support which is in place for the application activity and any relevant restrictions around this.

Any amendments which are made to the scope of this support, including but not limited to, purpose, data flows, data sources, items of confidential patient information and processors, require submission of a formal amendment to the application. The amendment form can be found in the 'Guidance for CAG Applicants' section of the Health Research Authority website.

Support for any submitted amendment would not come into effect until a further outcome letter has been issued.

Changes to the controller

Amendments which involve a change to the named controller for the application activity require the submission of a new CAG application form to support the application amendment. This is necessary to ensure that the application held on file appropriately reflects the organisation taking responsibility for the manner and purpose of data processing within the application.

Applicants are advised to make contact with the Confidentiality Advice Team to discuss a change in controllership for an existing application in sufficient time ahead of the transfer of project responsibility to discuss the submission process.

Reviewed documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
CAG application from (signed/authorised) [CAG_RD_Form_ReadyForSubmission_05072019]		05 July 2019
Covering letter on headed paper [CAG deferred outcome Response Oct 19 v2]	2	19 October 2019
Covering letter on headed paper [Re_ 19CAG0220 Provisional Outcome (to Applicant)]		16 December 2019
Other [19CAG0220 CAT advice form v1.4 26.04.2019 response]		
Other [reply_from_dfe]		19 February 2019
REC favourable opinion letter and all correspondence [188069 16EM0440 SA1 FO 04.02.19]		04 February 2019
Research protocol or project proposal [DATA FLOW CHART v10CAG]	10	19 November 2019
Research protocol or project proposal [Protocol v5 19122018 clean]	519/12/2018	
Written recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [DirectorRecomendation phw 050719]		05 July 2019

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item are listed below.

There were no declarations of interest in relation to this item.

User Feedback

The Health Research Authority is continually striving to provide a high-quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R & D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

With the Group's best wishes for the success of this project.

Yours sincerely

Kathleen Cassidy
Confidentiality Advisor

On behalf of the Health Research Authority

Email: HRA.CAG@nhs.net

Included:	List of members who considered application Standard conditions of support
Copy to:	nrescommittee.eastmidlands-derby@nhs.net hra.approval@nhs.net

Confidentiality Advisory Group Sub-Committee meeting attendance
December 2019

Members present:

Name	
Dr Tony Calland MBE	CAG Chair
Mr David Evans	CAG member
Dr Liliane Field	CAG member
Mr. Myer Glickman	CAG member
Ms Gillian Wells	CAG member

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	HRA Confidentiality Advisor

Health Research Authority

Standard conditions of support

Support to process the specified confidential patient information without consent, given by the Health Research Authority, is subject to compliance with the following standard conditions of support.

The applicant and those processing the information under the terms of the support will ensure that:

1. The specified confidential patient information is only used for the purpose(s) set out in the application.

2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.

3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant, in addition to other national guidance.

4. All staff with access to confidential patient information have contractual obligations of confidentiality, enforceable through disciplinary procedures.

5. All staff with access to confidential patient information have received appropriate ongoing training to ensure they are aware of their responsibilities and are acting in compliance with the application detail.

6. Activities must be compliant with the General Data Protection Regulation and Data Protection Act 2018.

7. Audit of data processing by a designated agent is facilitated and supported.

8. The wishes of patients who have withheld or withdrawn their consent are respected.

9. Any significant changes (for example, people, purpose, data flows, data items, security arrangements) must be approved via formal amendment prior to changes coming into effect.

10. An annual review report is submitted to the CAG every 12 months from the date of the final support letter, for the duration of the support.

11. Any breaches of confidentiality around the supported flows of information should be reported to CAG within 10 working days of the incident, along with remedial actions taken/to be taken. This does not remove the need to follow national/legal requirements for reporting relevant security breaches.